UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

| IN RE: ETHICON PHYSIOMESH |) | |
|---------------------------|---|---------------------|
| FLEXIBLE COMPOSITE |) | MDL DOCKET NO. 2782 |
| HERNIA MESH PRODUCTS |) | |
| LIABILITY LITIGATION |) | |
| |) | |
| |) | CIVIL ACTION NO. |
| This Document Relates to |) | 1:17-MD-02782-RWS |
| ALL CASES |) | |
| |) | |

MASTER ANSWER AND JURY DEMAND OF DEFENDANT JOHNSON & JOHNSON TO MASTER LONG FORM COMPLAINT

Defendant Johnson & Johnson responds to plaintiffs' Master Long Form Complaint ("Complaint") as follows:

The unnumbered introductory paragraph of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson.

I. RESPONSE TO "PARTIES"

RESPONSE TO "PLAINTIFFS"

1. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson admits

that Ethicon, Inc. designed, manufactured, distributed, and sold PHYSIOMESHTM Flexible Composite Mesh ("Physiomesh") for uses consistent with the packaging and labeling. Johnson & Johnson admits further that Ethicon, Inc. designed, distributed and sold SECURESTRAP® Absorbable Strap Fixation Device ("SecureStrap") for uses consistent with the packaging and labeling, but denies that Ethicon, Inc. manufactured that device. Johnson & Johnson does not design, manufacture, distribute or sell any product. Johnson & Johnson denies all remaining allegations contained in Paragraph 1 of plaintiffs' Complaint and all allegations inconsistent with the foregoing. Johnson & Johnson specifically denies that the term "Physiomesh" "includes the product with and without the SecureStrap fixation device." SecureStrap and Physiomesh are separate and distinct products, and this Multi-District Litigation concerns Physiomesh, not SecureStrap.

2. The allegations contained in Paragraph 2 of plaintiffs' Complaint do not require a response from Johnson & Johnson. If Johnson & Johnson is mistaken in that regard, then Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson also lacks sufficient knowledge or information so as to form a belief as to the truth of the

remaining allegations contained in Paragraph 2 of plaintiffs' Complaint and, therefore, denies those allegations.

RESPONSE TO "DEFENDANTS"

- 3. Johnson & Johnson admits that it is a business corporation organized under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza in New Brunswick, New Jersey. Any information contained on Johnson & Johnson's website speaks for itself. Johnson & Johnson denies all allegations contained in Paragraph 3 of plaintiffs' Complaint that are inconsistent with the foregoing.
- 4. With respect to the allegations contained in Paragraph 4 of the Complaint, Johnson & Johnson is a holding company for companies with a primary focus of providing products and services related to human health and wellbeing. Each of these subsidiary companies operates independently of Johnson & Johnson & Johnson's subsidiaries are organized in three business segments: Consumer, Pharmaceutical and Medical Devices. The companies within these segments are financially and operationally independent. Johnson & Johnson admits that Ethicon, Inc. designed, developed, manufactured, tested, marketed, promoted, distributed, and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson further admits that Ethicon, Inc. designed,

developed, marketed, promoted, distributed, and sold SecureStrap for uses consistent with the packaging and labeling. Johnson & Johnson denies that Ethicon, Inc. manufactured SecureStrap. Johnson & Johnson does not design, develop, manufacture, test, market, promote, distribute or sell any product. Johnson & Johnson further admits that Mr. Gary Pruden in 2009 became Company Group Chairman, Ethicon. In 2012, he was named Worldwide Chairman, Global Surgery Group, and in 2015, Worldwide Chairman, Medical Devices. Mr. Pruden retired effective June 1, 2017. Johnson & Johnson denies the remaining allegations contained in Paragraph 4 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

- 5. Johnson & Johnson admits only that Ethicon, Inc. is a business corporation organized under the laws of the State of New Jersey with its principal place of business in Somerville, New Jersey, and that it is a wholly owned subsidiary of Johnson & Johnson & Johnson denies the remaining allegations contained in Paragraph 5 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 6. Johnson & Johnson admits that Ethicon, Inc. researched, developed, tested, manufactured, produced, marketed, promoted, and/or sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson further admits

that Ethicon, Inc. researched, developed, tested, marketed, promoted, and sold SecureStrap for uses consistent with the packaging and labeling. Johnson & Johnson denies that Ethicon, Inc. manufactured SecureStrap. Johnson & Johnson does not research, develop, test, manufacture, produce, market, promote or sell any product. Physiomesh and SecureStrap are distinct products, and were sold separately. Johnson & Johnson denies the remaining allegations contained in Paragraph 6 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

7. Johnson & Johnson admits only that Ethicon, Inc. researched, developed, designed, manufactured, produced, tested, marketed, promoted, distributed, and/or sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, develop, design, manufacture, produce, test, market, promote, distribute or sell any product. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 7 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

- 8. Johnson & Johnson denies the allegations contained in Paragraph 8 of plaintiffs' Complaint.
- 9. Johnson & Johnson denies the allegations contained in Paragraph 9 of plaintiffs' Complaint.
- 10. The first sentence of Paragraph 10 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Johnson & Johnson & Johnson & Johnson denies that plaintiffs' Complaint accurately or completely states the nature of any duties allegedly owed by Defendants and Johnson & Johnson further denies that Defendants breached any duty with respect to the plaintiffs. Physiomesh is safe and effective for uses consistent with the packaging and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 10 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

II. RESPONSE TO "JURISDICTION AND VENUE"

- 11. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 11 of plaintiffs' Complaint, and, therefore, denies those allegations.
- 12. Paragraph 12 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Johnson & Johnson. To

the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 12 of plaintiffs' Complaint.

13. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 13 of plaintiffs' Complaint, and, therefore, denies those allegations. The second sentence of Paragraph 13 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 13 of plaintiffs' Complaint.

III. RESPONSE TO "FACTS COMMON TO ALL COUNTS"

- 14. Johnson & Johnson admits only that Ethicon, Inc. manufactured, sold, and/or distributed Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not manufacture, sell or distribute any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 14 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 15. Johnson & Johnson admits only that Ethicon, Inc. researched, designed, developed, tested, manufactured, produced, marketed, promoted, distributed, and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not research, design, develop, test, manufacture,

produce, market, promote, distribute or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 15 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

- 16. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, or the circumstances under which any particular plaintiff may have used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies those allegations. Johnson & Johnson admits only that Ethicon, Inc. designed, manufactured, and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 16 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 17. Johnson & Johnson admits only that Physiomesh is safe and effective for uses consistent with the packing and labeling. Johnson & Johnson denies the remaining allegations contained in Paragraph 17 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 18. Johnson & Johnson denies the allegations contained in Paragraph 18 of plaintiffs' Complaint.

- 19. Johnson & Johnson admits only that Physiomesh has five layers, including two layers of Monocryl film and a layer of polydioxanone film and that Ethicon, Inc. promoted Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not promote any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 19 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 20. Johnson & Johnson denies the allegations contained in Paragraph 20 of plaintiffs' Complaint.
- 21. Johnson & Johnson denies the allegations contained in Paragraph 21 of plaintiffs' Complaint.
- 22. Johnson & Johnson denies the allegations contained in Paragraph 22 of plaintiffs' Complaint.
- 23. Johnson & Johnson denies the allegations contained in Paragraph 23 of plaintiffs' Complaint.
- 24. Johnson & Johnson denies the allegations contained in Paragraph 24 of plaintiffs' Complaint.
- 25. Johnson & Johnson denies the allegations contained in Paragraph 25 of plaintiffs' Complaint.

- 26. Johnson & Johnson denies the allegations contained in Paragraph 26 of plaintiffs' Complaint.
- 27. Johnson & Johnson denies the allegations contained in Paragraph 27 of plaintiffs' Complaint.
- 28. Johnson & Johnson denies the allegations contained in Paragraph 28 of plaintiffs' Complaint.
- 29. Johnson & Johnson admits only that Ethicon, Inc. designed and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 29 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 30. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson admits only that in May 2016 a notice was issued regarding Physiomesh, the content of which speaks for itself. Johnson & Johnson denies the remaining allegations contained in Paragraph 30 of plaintiffs' Complaint and denies all allegations inconsistent with the foregoing.

- 31. Johnson & Johnson denies the allegations contained in Paragraph 31 of plaintiffs' Complaint.
- 32. Johnson & Johnson denies the allegations contained in Paragraph 32 of plaintiffs' Complaint.
- 33. Johnson & Johnson denies the allegations contained in Paragraph 33 of plaintiffs' Complaint.
- 34. Johnson & Johnson denies the allegations contained in Paragraph 34 of plaintiffs' Complaint.

IV. RESPONSE TO "CAUSES OF ACTION"

RESPONSE TO "COUNT I Strict Product Liability: Defective Design"

- 35. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 36. Johnson & Johnson denies the allegations contained in Paragraph 36 of plaintiffs' Complaint.
- 37. Johnson & Johnson denies the allegations contained in Paragraph 37 of plaintiffs' Complaint.
- 38. Johnson & Johnson admits only that Ethicon, Inc. sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not

sell any product. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 38 of plaintiffs' Complaint and any allegation inconsistent with the foregoing.

- 39. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products and/or whether the alleged implantation of Physiomesh in any particular plaintiff's body was medically reasonable, and therefore Johnson & Johnson denies those allegations. Johnson & Johnson admits only that Ethicon, Inc. designed, manufactured, and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, manufacture or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 39 of plaintiffs' Complaint.
- 40. Johnson & Johnson denies the allegations contained in Paragraph 40 of plaintiffs' Complaint.
- 41. Johnson & Johnson admits only that Ethicon, Inc. marketed and promoted Physiomesh for uses consistent with the packaging and labeling and that the device is composed of both nonabsorbable and absorbable components.

Johnson & Johnson does not market or promote any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 41 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

- 42. Johnson & Johnson denies the allegations contained in Paragraph 42 of plaintiffs' Complaint.
- 43. Johnson & Johnson denies the allegations contained in Paragraph 43 of plaintiffs' Complaint.
- 44. Johnson & Johnson denies the allegations contained in Paragraph 44 of plaintiffs' Complaint.
- 45. Johnson & Johnson admits only that Ethicon, Inc. designed Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 45 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 46. Johnson & Johnson denies the allegations contained in Paragraph 46 of plaintiffs' Complaint.
- 47. Johnson & Johnson denies the allegations contained in Paragraph 47 of plaintiffs' Complaint.

- 48. Johnson & Johnson denies the allegations contained in Paragraph 48 of plaintiffs' Complaint.
- 49. Johnson & Johnson denies the allegations contained in Paragraph 49 of plaintiffs' Complaint.
- 50. Johnson & Johnson denies the allegations contained in Paragraph 50 of plaintiffs' Complaint.

RESPONSE TO "COUNT II Strict Product Liability: Failure to Warn"

- 51. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 52. Johnson & Johnson denies the allegations contained in Paragraph 52 of plaintiffs' Complaint.
- 53. Johnson & Johnson denies the allegations contained in Paragraph 53 of plaintiffs' Complaint.
- 54. Johnson & Johnson denies the allegations contained in Paragraph 54 of plaintiffs' Complaint.
- 55. Johnson & Johnson admits only that Ethicon, Inc. sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not sell any product. Johnson & Johnson lacks sufficient knowledge or information to

know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 55 of plaintiffs' Complaint and any allegation inconsistent with the foregoing.

- 56. Johnson & Johnson denies the allegations contained in Paragraph 56 of plaintiffs' Complaint.
- 57. Johnson & Johnson denies the allegations contained in Paragraph 57 of plaintiffs' Complaint.
- 58. Johnson & Johnson denies the allegations contained in Paragraph 58 of plaintiffs' Complaint.
- 59. Johnson & Johnson denies the allegations contained in Paragraph 59 of plaintiffs' Complaint.
- 60. Johnson & Johnson denies the allegations contained in Paragraph 60 of plaintiffs' Complaint.
- 61. Johnson & Johnson denies the allegations contained in Paragraph 61 of plaintiffs' Complaint.
- 62. Johnson & Johnson admits only that Ethicon, Inc. marketed and promoted Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not market or promote any product. Johnson & Johnson lacks

sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 62 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.

- 63. Johnson & Johnson denies the allegations contained in Paragraph 63 of plaintiffs' Complaint.
- 64. Johnson & Johnson denies the allegations contained in Paragraph 64 of plaintiffs' Complaint.
- 65. Johnson & Johnson denies the allegations contained in Paragraph 65 of plaintiffs' Complaint.
- 66. Johnson & Johnson denies the allegations contained in Paragraph 66 of plaintiffs' Complaint.
- 67. Johnson & Johnson denies the allegations contained in Paragraph 67 of plaintiffs' Complaint.

RESPONSE TO "COUNT III Strict Product Liability: Manufacturing Defect"

68. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

- 69. Johnson & Johnson denies the allegations contained in Paragraph 69 of plaintiffs' Complaint.
- 70. Johnson & Johnson denies the allegations contained in Paragraph 70 of plaintiffs' Complaint.
- 71. Johnson & Johnson denies the allegations contained in Paragraph 71 of plaintiffs' Complaint.
- 72. Johnson & Johnson denies the allegations contained in Paragraph 72 of plaintiffs' Complaint.
- 73. Johnson & Johnson denies the allegations contained in Paragraph 73 of plaintiffs' Complaint.
- 74. Johnson & Johnson denies the allegations contained in Paragraph 74 of plaintiffs' Complaint.
- 75. Johnson & Johnson denies the allegations contained in Paragraph 75 of plaintiffs' Complaint.

RESPONSE TO "COUNT IV Negligence"

76. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.

- 77. Paragraph 77 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Johnson & Johnson. Johnson & Johnson denies that plaintiffs' Complaint accurately or completely sets forth any alleged duties owed by Defendants, and Johnson & Johnson further denies that Defendants breached any duty with respect to the plaintiffs. Johnson & Johnson admits that Ethicon, Inc. designed, tested, manufactured, marketed, and distributed Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not design, test, manufacture, market or distribute any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 77 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 78. Johnson & Johnson denies the allegations contained in Paragraph 78 of plaintiffs' Complaint.
- 79. Johnson & Johnson denies the allegations contained in Paragraph 79 of plaintiffs' Complaint.
- 80. Johnson & Johnson denies the allegations contained in Paragraph 80 of plaintiffs' Complaint, including subparts (a.) (g.).
- 81. Johnson & Johnson denies the allegations contained in Paragraph 81 of plaintiffs' Complaint, including subparts (a.) (h.).

- 82. Johnson & Johnson denies the allegations contained in Paragraph 82 of plaintiffs' Complaint, including subparts (a.) (t.).
- 83. Johnson & Johnson denies the allegations contained in Paragraph 83 of plaintiffs' Complaint.
- 84. Johnson & Johnson denies the allegations contained in Paragraph 84 of plaintiffs' Complaint.
- 85. Johnson & Johnson denies the allegations contained in Paragraph 85 of plaintiffs' Complaint.
- 86. Johnson & Johnson denies the allegations contained in Paragraph 86 of plaintiffs' Complaint.

RESPONSE TO "COUNT V Consumer Protection Laws"

- 87. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 88. Johnson & Johnson lacks sufficient knowledge or information to know whether any particular plaintiff used any of Ethicon, Inc.'s products, and therefore Johnson & Johnson denies that allegation. Johnson & Johnson denies the remaining allegations contained in Paragraph 88 of plaintiffs' Complaint.

- 89. Johnson & Johnson denies the allegations contained in Paragraph 89 of plaintiffs' Complaint.
- 90. Johnson & Johnson denies the allegations contained in Paragraph 90 of plaintiffs' Complaint.
- 91. Johnson & Johnson denies the allegations contained in Paragraph 91 of plaintiffs' Complaint, including subparts (a.) (c.).
- 92. Johnson & Johnson denies the allegations contained in Paragraph 92 of plaintiffs' Complaint.
- 93. Paragraph 93 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Johnson & Johnson. Johnson & Johnson denies that plaintiffs' Complaint accurately or completely states the nature of any duties allegedly owed by Defendants and Johnson & Johnson further denies that Defendants breached any duty with respect to the plaintiffs. Johnson & Johnson denies the remaining allegations contained in Paragraph 93 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 94. Johnson & Johnson denies the allegations contained in Paragraph 94 of plaintiffs' Complaint.

- 95. Paragraph 95 of plaintiffs' Complaint states a legal conclusion as opposed to a factual allegation and requires no response by Johnson & Johnson. Johnson & Johnson denies that plaintiffs' Complaint accurately or completely states the nature of the referenced statutes. Johnson & Johnson admits only that Ethicon, Inc. supplied, manufactured, and sold Physiomesh for uses consistent with the packaging and labeling. Johnson & Johnson does not supply, manufacture or sell any product. Johnson & Johnson denies the remaining allegations contained in Paragraph 95 of plaintiffs' Complaint and all allegations inconsistent with the foregoing.
- 96. Johnson & Johnson denies the allegations contained in Paragraph 96 of plaintiffs' Complaint.
- 97. Johnson & Johnson denies the allegations contained in Paragraph 97 of plaintiffs' Complaint.
- 98. Johnson & Johnson denies the allegations contained in Paragraph 98 of plaintiffs' Complaint.
- 99. Johnson & Johnson denies the allegations contained in Paragraph 99 of plaintiffs' Complaint.

RESPONSE TO "COUNT VI Gross Negligence"

- 100. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 101. Johnson & Johnson denies the allegations contained in Paragraph 101 of plaintiffs' Complaint.
- 102. Johnson & Johnson denies the allegations contained in Paragraph 102 of plaintiffs' Complaint.
- 103. Paragraph 103 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies that any plaintiff is entitled to any recovery or any form of relief whatsoever from Johnson & Johnson and denies the remaining allegations contained in Paragraph 103 of plaintiffs' Complaint.
- 104. Johnson & Johnson denies the allegations contained in Paragraph 104 of plaintiffs' Complaint.

RESPONSE TO "COUNT VII Loss of Consortium"

- 105. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 106. Johnson & Johnson denies the allegations contained in the first sentence of Paragraph 106 of plaintiffs' Complaint. The second sentence of Paragraph 106 makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies any liability to any of the plaintiffs.
- 107. Johnson & Johnson denies the allegations contained in Paragraph 107 of plaintiffs' Complaint.
- 108. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 108 of plaintiffs' Complaint, and, therefore, denies those allegations. Johnson & Johnson denies any liability to any of the plaintiffs.
- 109. Johnson & Johnson lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations contained in Paragraph 109 of plaintiffs' Complaint, and, therefore, denies those allegations. Johnson & Johnson denies any liability to any of the plaintiffs.

110. Johnson & Johnson denies the allegations contained in Paragraph 110 of plaintiffs' Complaint.

RESPONSE TO "COUNT VIII Punitive Damages"

- 111. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 112. Johnson & Johnson denies the allegations contained in Paragraph 112 of plaintiffs' Complaint.
- 113. Johnson & Johnson denies the allegations contained in Paragraph 113 of plaintiffs' Complaint.
- 114. Johnson & Johnson denies the allegations contained in Paragraph 114 of plaintiffs' Complaint.
- 115. Johnson & Johnson denies the allegations contained in Paragraph 115 of plaintiffs' Complaint.
- 116. Johnson & Johnson denies the allegations contained in Paragraph 116 of plaintiffs' Complaint.
- 117. Johnson & Johnson denies the allegations contained in Paragraph 117 of plaintiffs' Complaint.

- 118. Johnson & Johnson denies the allegations contained in Paragraph118 of plaintiffs' Complaint.
- 119. Johnson & Johnson denies the allegations contained in Paragraph 119 of plaintiffs' Complaint.
- 120. Johnson & Johnson denies the allegations contained in Paragraph 120 of plaintiffs' Complaint.

RESPONSE TO "COUNT IX Discovery Rule, Equitable Tolling/Estoppel"

- 121. Johnson & Johnson incorporates by reference its responses to each and every allegation contained in plaintiffs' Complaint as if fully copied and set forth at length herein.
- 122. Paragraph 122 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 122 of plaintiffs' Complaint.
- 123. Paragraph 123 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 123 of plaintiffs' Complaint.

- 124. Paragraph 124 of plaintiffs' Complaint makes no allegation against Johnson & Johnson and requires no response by Johnson & Johnson. To the extent a response is required, Johnson & Johnson denies the allegations contained in Paragraph 124 of plaintiffs' Complaint.
- 125. Johnson & Johnson denies the allegations contained in Paragraph 125 of plaintiffs' Complaint.

RESPONSE TO "PRAYER FOR RELIEF"

In response to the unnumbered "WHEREFORE" paragraph in plaintiffs' PRAYER FOR RELIEF, Johnson & Johnson demands a jury trial and denies that any plaintiff is entitled to any recovery, including subparts (1.) – (9.), or any form of relief whatsoever from Johnson & Johnson & Johnson & Johnson respectfully requests that the Complaint be dismissed with prejudice with all costs assessed to plaintiffs and for any such other general or special relief as may be appropriate. Johnson & Johnson denies the remaining allegations contained in this paragraph.

Johnson & Johnson denies any and all allegations contained in plaintiffs' Complaint not specifically admitted hereinabove.

DEFENSES

By asserting the following defenses, Johnson & Johnson does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters.

FIRST DEFENSE

The Court's jurisdiction over these matters derives from a Transfer Order of the United States Judicial Panel on Multidistrict Litigation. That Order did not confer jurisdiction over claims associated with any product other than Physiomesh. SecureStrap is a separate and distinct product and the allegations in plaintiffs' Complaint relating to SecureStrap are not properly before the Court.

SECOND DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred because Johnson & Johnson does not design, develop, manufacture, market, promote or sell any product allegedly at issue in this action.

THIRD DEFENSE

Johnson & Johnson has never had possession or control over the product at issue in this action, and, therefore, the Complaint as to each cause of action fails to state a claim against Johnson & Johnson.

FOURTH DEFENSE

The Complaint fails, in whole or in part, to state a cause of action upon which relief can be granted.

FIFTH DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted due to lack of adequate product identification.

SIXTH DEFENSE

Plaintiffs' claims are barred for lack of subject matter jurisdiction.

SEVENTH DEFENSE

Plaintiffs' claims are barred for lack of personal jurisdiction.

EIGHTH DEFENSE

The Complaint must be dismissed because plaintiffs provided insufficient process.

NINTH DEFENSE

The Complaint must be dismissed because plaintiffs provided insufficient service of process.

TENTH DEFENSE

Plaintiffs may be barred from bringing some of the claims alleged in the Complaint because plaintiffs may lack standing and/or capacity to bring such claims.

ELEVENTH DEFENSE

Certain of plaintiffs' claims and remedies and the defenses thereto are governed by the laws of a foreign jurisdiction or the laws of the United States.

TWELFTH DEFENSE

Plaintiffs may have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

THIRTEENTH DEFENSE

Venue in this Court is improper.

FOURTEENTH DEFENSE

This matter should be dismissed on intra-state or interstate forum non conveniens grounds.

FIFTEENTH DEFENSE

Johnson & Johnson reserves and does not waive all rights under *Lexecon*, *Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). Johnson & Johnson specifically reserves its rights as it relates to venue and personal jurisdiction.

SIXTEENTH DEFENSE

Plaintiffs' alleged causes of action have been improperly joined under the applicable Rules of Civil Procedure and the laws of the applicable state.

SEVENTEENTH DEFENSE

The improper joinder of plaintiffs' alleged causes of action violates the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state, as well as the applicable Rules of Civil Procedure and the laws of the applicable state.

EIGHTEENTH DEFENSE

The improper joinder of Defendants violates the procedural and substantive due process rights of Johnson & Johnson under the Constitutions of the United States of America and the applicable state.

NINETEENTH DEFENSE

Johnson & Johnson specifically pleads, to the extent plaintiffs plead claims based on allegations of fraud, deceit by concealment and negligent misrepresentation claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

TWENTIETH DEFENSE

Johnson & Johnson is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in any state whose law is deemed to apply in this case.

TWENTY-FIRST DEFENSE

Plaintiffs' claims are barred by the doctrine of federal preemption, as established by statute, including the preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and by state and federal case law, and are barred by the Supremacy Clause of the United States Constitution, because the product at issue is regulated by the United States Food and Drug Administration ("FDA") under the Medical Device Amendments, 21 U.S.C. §§ 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations.

TWENTY-SECOND DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. At all relevant times, however, the product was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. §§ 360k, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and other federal statutes and regulations, and plaintiffs' claims are accordingly barred.

TWENTY-THIRD DEFENSE

Plaintiffs' claims against Johnson & Johnson are expressly and/or impliedly preempted by federal law, including but not limited to the regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. *See* 21 U.S.C. §§ 301 *et seq.*; *see also* Fed. Reg. 3922 (Jan. 24, 2006).

TWENTY-FOURTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. Plaintiffs' claims nevertheless are barred because the entity responsible for the design, development, manufacture, licensing, marketing, distribution and/or sale of the product complied with all applicable state and federal statutes regarding the product at issue including the requirements and regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations. In the event that plaintiffs' claims are not barred, Johnson & Johnson and the entity responsible for the design, development, manufacture, licensing, marketing, distribution and/or sale of the product are entitled to a presumption that the product at issue is free from any defect or defective condition as the plans or design for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were in conformity with government standards established for the

industry that were in existence at the time the plans or designs for the product at issue or the methods and techniques of manufacturing, inspecting, and testing the product at issue were adopted.

TWENTY-FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the deference that federal and state constitutional law and federal and state common law give to discretionary actions by the FDA under the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder.

TWENTY-SIXTH DEFENSE

Plaintiffs' claims are barred by any applicable safe harbor doctrine to the extent federal law permits the packaging, labeling, and marketing practices alleged in the Complaint.

TWENTY-SEVENTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. However, plaintiffs' claims are governed and barred, in whole or in part, by Sections 2, 4, and 6 of The Restatement (Third) of Torts (including the comments thereto) because the entity responsible for the design, development, manufacture, licensing, marketing, distribution, sale and/or placing the product in the stream of commerce

complied with all applicable statutes and with the requirements and regulations of the FDA.

TWENTY-EIGHTH DEFENSE

Any claims by plaintiffs relating to alleged communications with regulatory agencies in the United States government are barred in whole or in part by operation of applicable law, including the First Amendment rights of Johnson & Johnson to petition the government.

TWENTY-NINTH DEFENSE

Johnson & Johnson does not manufacture, market, label, promote, distribute or sell any product nor has it ever had possession or control over the product at issue in this action. In any event, plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under the law with determining the content of warnings and labeling for medical devices.

THIRTIETH DEFENSE

Johnson & Johnson does not manufacture, market, label, promote, distribute or sell any product nor has it ever had possession or control over the product at issue in this action. In any event, plaintiffs cannot state a claim with regard to

warnings and labeling for medical devices because the remedy sought by plaintiffs is subject to the exclusive regulations of FDA.

THIRTY-FIRST DEFENSE

Plaintiffs' claim for punitive damages is barred because the product at issue was manufactured and labeled in accordance with the terms of FDA's clearance of the product at issue.

THIRTY-SECOND DEFENSE

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer design for the product at issue.

THIRTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue provided a benefit to users of such product and greatly outweighed any risk created by using such product, any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time, the benefit provided to users could not be achieved in another manner with less risk, and adequate warnings concerning the risk were provided.

THIRTY-FOURTH DEFENSE

Johnson & Johnson made no express or implied representations or warranties of any kind to plaintiffs, nor did plaintiffs rely on any representations or

warranties made by Johnson & Johnson to others. To the extent plaintiffs relied upon any representations or warranties, such reliance was unjustified.

THIRTY-FIFTH DEFENSE

Any express or implied warranties alleged to have been made by Johnson & Johnson were disclaimed.

THIRTY-SIXTH DEFENSE

Johnson & Johnson did not make nor did it breach any express or implied warranties and/or breach any warranties created by law. To the extent that plaintiffs rely on any theory of breach of warranty, such claims are barred by applicable law, by the lack of privity between plaintiffs and Johnson & Johnson, and/or by plaintiffs' failure to give Johnson & Johnson timely notice of the alleged breach of warranty and an opportunity to cure. Johnson & Johnson further specifically pleads as to any breach of warranty claim all affirmative defenses available to Johnson & Johnson under the Uniform Commercial Code, as enacted in any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

THIRTY-SEVENTH DEFENSE

To the extent that any of plaintiffs' claims can be, or are construed as, alleging a violation of consumer protection laws, Johnson & Johnson specifically

pleads all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under the common law principles of any state whose law is deemed to apply in this case.

THIRTY-EIGHTH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, were not foreseeable to Johnson & Johnson given the state of scientific knowledge and state-of-the-art at the time of the alleged injuries. At all times relevant, the product at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such product at that time, as well as all applicable statutes and regulations, including those of FDA.

THIRTY-NINTH DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and thus the "last clear chance" and assumption of the risk doctrines bar in whole or in part the damages that plaintiffs seek to recover herein.

FORTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the entity responsible for the product acted in good faith at all relevant times and gave

adequate warnings of all known or reasonably knowable risks associated with the use of the product at issue.

FORTY-FIRST DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. At all relevant times herein, however, the product in question was manufactured and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

FORTY-SECOND DEFENSE

Plaintiffs' inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

FORTY-THIRD DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was consistent with and/or exceeded consumer expectations.

FORTY-FOURTH DEFENSE

Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. Plaintiffs' claims are barred in whole or in part, however, because the product at issue was at all times properly prepared, packaged, and distributed and was not defective or unreasonably dangerous.

FORTY-FIFTH DEFENSE

Adequate and complete warnings and instructions were provided with the product at issue. Johnson & Johnson does not design, develop, manufacture, license, market, distribute, sell and/or place in the stream of commerce any product. The product at issue, however, was neither defective nor unreasonably dangerous when used according to its Instructions for Use.

FORTY-SIXTH DEFENSE

At all relevant times, the warnings and instructions accompanying the product at issue were governed by and conformed with applicable federal statutes, rules and regulations; therefore, warnings and instructions relating to the product were presumptively adequate.

FORTY-SEVENTH DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine.

FORTY-EIGHTH DEFENSE

Johnson & Johnson is not liable to plaintiffs because the end users of the product at issue, plaintiffs' physicians, were sophisticated users of the product.

<u>FORTY-NINTH DEFENSE</u>

Johnson & Johnson states that the sole proximate cause of the injuries and/or damages alleged by plaintiffs was the actions, omissions, or negligence of a person or persons, other than Johnson & Johnson, for whose actions, omissions, or

negligence Johnson & Johnson is in no way liable. Plaintiffs are not, therefore, entitled to recover from Johnson & Johnson in this action. As to plaintiffs or to any other entity or person whose conduct or intervening negligence resulted in the alleged injuries and/or damages of plaintiffs, if any, Johnson & Johnson expressly pleads the doctrines of assumption of risk, contributory negligence, comparative fault and/or comparative negligence, as well as the provisions of any applicable comparative fault and/or comparative negligence and/or contributory negligence statute, law or policy of any applicable state.

FIFTIETH DEFENSE

The injuries and damages allegedly suffered in this action, which are denied, may have been caused, in whole or in part, by plaintiffs' own fault, which bars or proportionately reduces Johnson & Johnson's liability, if any, for plaintiffs' alleged damages.

FIFTY-FIRST DEFENSE

Plaintiffs voluntarily and unreasonably chose to encounter known dangers.

FIFTY-SECOND DEFENSE

The liability of Johnson & Johnson, if any, for plaintiffs' non-economic loss must be apportioned in accordance with the provisions of the law of any applicable state.

FIFTY-THIRD DEFENSE

In the event Johnson & Johnson is held liable to plaintiffs, which liability is expressly denied, and any other co-defendants are also held liable, Johnson & Johnson is entitled to a percentage contribution of the total liability from said co-defendants in accordance with principles of equitable indemnity and comparative contribution and pursuant to any applicable contribution or apportionment statute, law or policy of the applicable states.

FIFTY-FOURTH DEFENSE

There is no causal relationship between Johnson & Johnson's conduct and the injuries and damages alleged by plaintiffs in the Complaint.

FIFTY-FIFTH DEFENSE

At all times mentioned herein, plaintiffs were negligent, careless and at fault and conducted themselves so as to contribute substantially to their alleged injuries, losses, and damages. Said negligence, carelessness and fault of plaintiffs bars in whole or in part the damages which plaintiffs seek to recover herein.

FIFTY-SIXTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were solely caused by and attributable to the abnormal, unforeseeable, unintended, unreasonable, and improper use or misuse which was made of said product.

FIFTY-SEVENTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

FIFTY-EIGHTH DEFENSE

Plaintiffs' alleged injuries, losses, or damages attributable to the product at issue in this case, if any, were caused by the acts or omissions of third parties for which Johnson & Johnson has no legal responsibility.

FIFTY-NINTH DEFENSE

Johnson & Johnson expressly denies any third party engaging in the acts alleged by plaintiffs was acting as Johnson & Johnson's agent or servant, at the instruction of Johnson & Johnson, or within its control. Therefore, plaintiffs' claims, to the extent they seek to recover for the acts or omissions of such third parties, are barred in whole or in part as a matter of law.

SIXTIETH DEFENSE

Plaintiffs' causes of action are barred because the injuries and damages allegedly suffered in this action, which are denied, were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident, or preexisting condition, and/or

another unrelated medical, genetic or environmental condition, disease or illness, without any negligence or culpable conduct by Johnson & Johnson.

SIXTY-FIRST DEFENSE

Plaintiffs' claims are or may be barred by their failure to comply with conditions precedent to their right to recover.

SIXTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of avoidable consequences.

SIXTY-THIRD DEFENSE

The claims of plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence and the failure to properly preserve evidence necessary to the determination of the claims.

SIXTY-FOURTH DEFENSE

Plaintiffs' claims against Johnson & Johnson are barred by the doctrines of equitable estoppel, laches, consent, waiver, informed consent, release, unclean hands, res judicata, and collateral estoppel. Additionally, if any plaintiff had or has filed bankruptcy during the relevant time period of the events alleged in the Complaint or files for bankruptcy at some point in the future, the claims of any such plaintiff may be "property of the bankruptcy estate" which should be prosecuted by the bankruptcy trustee rather than plaintiff, or, if not disclosed by

plaintiff on the schedules and/or statement of financial affairs, may be barred by the doctrine of judicial estoppel.

SIXTY-FIFTH DEFENSE

Some or all of plaintiffs' claims may be barred by the statutes of limitations, prescription, and/or statutes of repose of any applicable state.

SIXTY-SIXTH DEFENSE

To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred by *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

SIXTY-SEVENTH DEFENSE

Plaintiffs' alleged damages, if any, are barred in whole or in part by plaintiffs' failure to mitigate such damages.

SIXTY-EIGHTH DEFENSE

The sale, labeling and marketing of the product at issue in this litigation is not, and was not, likely to mislead or deceive the public.

SIXTY-NINTH DEFENSE

The product at issue was altered after the product left the control, custody and possession of the entity responsible for the manufacture and distribution of the product at issue, and said alteration relieves such entity of any and all liability.

Johnson & Johnson has never had control, custody or possession over the product at issue in this action.

SEVENTIETH DEFENSE

Any strict liability cause of action for relief is subject to the limitations set forth in Restatement (Second) of Torts, Section 402A, comment k.

SEVENTY-FIRST DEFENSE

Plaintiffs' claims are barred in whole or in part under Section 402A, comments j and k of the Restatement (Second) of Torts.

SEVENTY-SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent plaintiffs have released, settled, entered into an accord and satisfaction or otherwise compromised their claims by any means.

SEVENTY-THIRD DEFENSE

Any recovery by plaintiffs must be reduced or offset by all amounts paid, payable by, or available from collateral sources.

SEVENTY-FOURTH DEFENSE

Plaintiffs' Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement or restitution.

SEVENTY-FIFTH DEFENSE

The Complaint fails to state facts sufficient to entitle plaintiffs to an award of punitive damages.

SEVENTY-SIXTH DEFENSE

No act or omission of Johnson & Johnson was malicious, oppressive, willful, wanton, reckless, or grossly negligent, and therefore any award of punitive damages is barred.

SEVENTY-SEVENTH DEFENSE

Plaintiffs' claims for pain and suffering are barred because they violate Johnson & Johnson's rights to procedural and substantive due process and equal protection as guaranteed by the Constitutions of the United States and any state whose law is deemed to apply in this case.

SEVENTY-EIGHTH DEFENSE

The imposition of punitive or exemplary damages would violate Johnson & Johnson's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, and the equivalent or correlative applicable provisions in the Constitutions, common law, public policy, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and the double jeopardy

clause in the Fifth Amendment to the Constitution of the United States. They would further violate Johnson & Johnson's rights to the extent that punitive damages awarded to any plaintiff are (1) imposed by a jury that is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of such a punitive damages award; is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment; is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidious discriminatory characteristics, including the corporate status, wealth, or state of residence of defendant; or is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; (2) not subject to independent de novo review by the trial and appellate courts for reasonableness and the furtherance of legitimate purposes on the basis of objective legal standards and in conformity with the United States Constitution as amended or any applicable State constitution as amended; (3) imposed where state law is impermissibly vague, imprecise, or inconsistent; (4) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount; (5) imposed on the basis of anything other than Johnson and Johnson's conduct within the State where each plaintiff resides; or (6) imposed in any other way subjecting Johnson & Johnson to impermissible multiple punishments for the same alleged wrong.

SEVENTY-NINTH DEFENSE

Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts of the applicable states under the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

EIGHTIETH DEFENSE

With respect to plaintiffs' demand for punitive damages, Johnson & Johnson specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards that arise under *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny, as applied by the federal courts of appeals, together with all such standards applicable under any other state's law.

EIGHTY-FIRST DEFENSE

Johnson & Johnson asserts the provisions of all applicable statutory caps on damages of any sort, including punitive, non-economic or exemplary damages, under the laws of any applicable state.

EIGHTY-SECOND DEFENSE

Johnson & Johnson specifically pleads as to plaintiffs' claims for punitive damages, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-THIRD DEFENSE

Johnson & Johnson specifically pleads as to plaintiffs' strict liability claims, all affirmative defenses available to Johnson & Johnson under the rules and statutes of any state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-FOURTH DEFENSE

Johnson & Johnson specifically pleads as to plaintiffs' negligence claims all affirmative defenses available to Johnson & Johnson under the rules and statutes of any other state whose law is deemed to apply in this case, and under any common law principles of any state whose law is deemed to apply in this case.

EIGHTY-FIFTH DEFENSE

Johnson & Johnson hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any codefendant in this lawsuit.

EIGHTY-SIXTH DEFENSE

The injuries complained of were not proximately caused by any product manufactured, sold or distributed by the entity responsible for such actions, nor were the injuries caused by any acts or omissions on the part of the entity responsible for the manufacturing, selling or distribution of the product at issue.

EIGHTY-SEVENTH DEFENSE

To the extent that plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Johnson's & Johnson's rights under the United States Constitution.

EIGHTY-EIGHTH DEFENSE

Johnson & Johnson is entitled to credit for any settlement of claims for alleged injuries and damages made by plaintiffs with any other defendant(s) or other person or entity subsequently joined to this action.

EIGHTY-NINTH DEFENSE

Plaintiffs' Complaint fails to state a claim for a manufacturing defect because such allegations fail to state a plausible claim for relief under the standards articulated in *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009), and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Accordingly, plaintiffs' manufacturing defect claim should be dismissed.

NINETIETH DEFENSE

As it relates to any causes of action asserted in a plaintiff's Short Form Complaint that are not included in the Complaint, Johnson & Johnson denies liability and relies on all defenses available under the law and equity.

NINETY-FIRST DEFENSE

Any causes of action that are alleged in a complaint that are not alleged in a subsequent Short Form Complaint are abandoned.

NINETY-SECOND DEFENSE

Johnson & Johnson reserves the right to assert any additional defenses and matters in avoidance, which may be disclosed during the course of additional investigation and discovery.

DEMAND FOR JURY TRIAL

Johnson & Johnson specifically requests and demands a trial by jury of 12 persons as to issues so triable.

WHEREFORE, Defendant Johnson & Johnson prays that:

(1) Plaintiffs take nothing by reason of their Complaint;

- (2) The Complaint be dismissed in its entirety and that a Judgment against plaintiffs and in favor of Johnson & Johnson be entered;
 - (3) Johnson & Johnson be awarded its costs and expenses; and
- (4) This Court award Johnson & Johnson any other and general or specific relief as this Court may deem just and proper.

Respectfully submitted,

/s/ William M. Gage

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Counsel for Defendants

FONT CERTIFICATION

Pursuant to Local Rule 7.1 D, I hereby certify that the foregoing document was prepared using Times New Roman 14 point type as provided in Local Rule 5.1.

s/ William M. Gage
William M. Gage